The Impedance Threshold Device (ITD-7) A New Device for Combat Casualty Care to Augment Circulation and Blood Pressure in Hypotensive Spontaneously Breathing Warfighters

Don Parsons, PA-C; Vic Convertino PhD; Ahamed Idris, MD; Stephen Smith, MD; David Lindstrom, MD; Brent Parquette, Medic; Tom Aufderheide, MD

Disclosure: None of the authors work for or have any financial interest or investment with the manufacturer of the impedance threshold device (ITD-7).

Abstract

Inspiration through -7cm H2O resistance results in an increase in venous blood flow back to the heart and a subsequent increase in cardiac output and blood pressure in hypotensive animals and patients. Breathing through the impedance threshold device with 7cm H2O resistance (ITD-7) also reduces intracranial pressure with each inspiration, thereby providing greater blood flow to the brain. A new device called an ITD-7 was developed to exploit these physiological mechanisms to *buy time* in hypotensive War Fighters when other therapies are not readily available. Animal and clinical data with the ITD-7 demonstrate the potential value and limitations of this new non-invasive approach to enhancing circulation.

ITD-7 with Facemask

ITD-7 Mouthpiece

Figure 1: *ITD-7 used with facemask (head strap and O2 attached) or mouthpiece.*

Introduction

This primer highlights an important new device, the impedance threshold device (ITD-7) (Figure 1), that can enhance circulation to the heart and brain in the care of spontaneously-breathing hypotensive Soldiers. The ITD-7 has been shown in animal and human studies to be useful as a new way to buy time between the onset of injury and when more definitive therapy is available. A better understanding of this device, which is based upon the fundamental mechanisms that regulate blood pressure during hemorrhage and hypotension, will help optimize care in warfighters wounded in battle. This simple non-invasive countermeasure helps protect against life-

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threatening hypotension by restoring central blood volume through enhancement of venous blood flow back to the heart with each inspiratory effort.

How it works

The Physiology

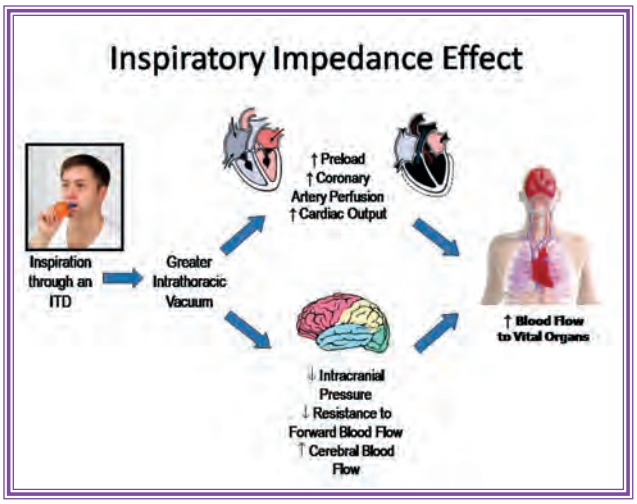

Figure 2: *How the IDT-7 works, shown attached to a mouthpiece.*

Significant blood loss leads to severe hypotension in the wounded warfighter because of reduction in cardiac filling and stroke volume. Increased negative intrathoracic pressure during spontaneous inspiration is a natural mechanism for enhancing venous return and cardiac refilling. (Figure 2) The ITD-7 is designed to non-invasively harness that natural physiology to increase venous return and stroke volume, serving as an effective countermeasure against cardiovascular collapse. Taking advantage of this natural physiology, application of this new device during spontaneous inspiration causes an immediate increase in arterial blood pressure in the setting of severe hypotension. The 7cm H2O inspiratory resistance induced by the ITD-7 results in a greater vacuum within the thorax during each inspiration and subsequently enhances refilling of the heart and also lowers intracranial pressure. These two mechanisms (refilling of the heart and lowering of intracranial pressure) contribute to the increase in blood flow to the heart and brain when using the device. Application of the device can therefore be used to rapidly increase blood pressure in hypotensive spontaneously breathing Soldiers when more definitive therapy is not yet available. It has some additional advantages as it does not cause hemodilution and, unlike many other types of resuscitative measures, it can be immediately removed following hemodynamic stabilization.

Device Testing

The ITD-7 was tested in animal models of hemorrhagic shock and heat stroke, in human volunteers, and in hypotensive patients in the emergency department and in dialysis clinics.[1-11] In pigs in hemorrhagic shock, the ITD increased systolic and diastolic blood pressure, enhanced blood flow to the heart and brain, and extended the *golden hour* of survival.[6,7,10] (Figure 3) In volunteers

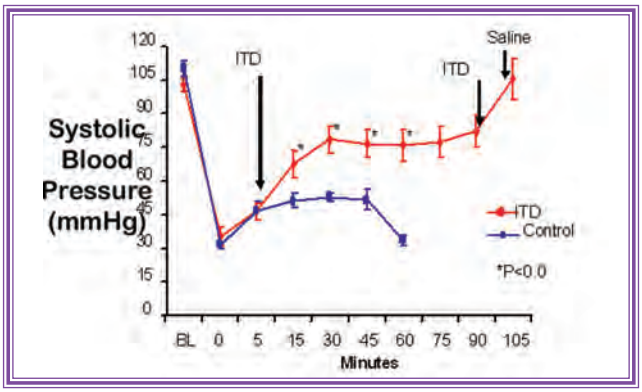

Figure 3: *Benefit of an impedance threshold device (ITD) on blood pressure in pigs with hemorrhagic shock*

tested at NASA , an ITD with a resistance of 7cm H2O was well tolerated. It also increased cardiac output in normal subjects by 1.5L/min, and prevented symptoms associated with acute orthostatic hypotension.[1,2,4] The ITD has an inspiratory resistance of 7cm H2O and no expiratory resistance. In volunteers tested at the U.S. Army Institute for Surgical Research, a prototypic ITD was shown to increase blood flow to the brain and significantly delay the onset of hypotension in volunteers subjected to severe hypotension induced by lower body negative pressure to simulate hemorrhagic shock.[1,3,9]

In hypotensive patients the ITD-7 increased systolic blood pressures and was well tolerated.[2,5,8,11] In the absence of an IV, hypotensive patients treated with the ITD-7 by medics outside the hospital or by medical per-

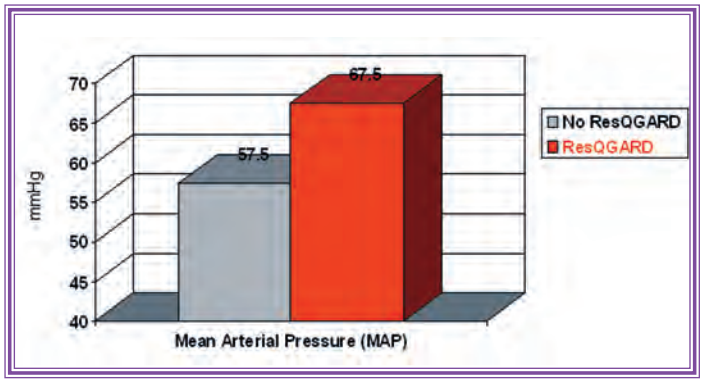

Figure 4: *IDT-7 (ResQGARD) increases mean arterial pressure (MAP) in hypotensive patients*

sonnel in the emergency department benefited immediately. With ITD-7 application there was a rise in mean arterial pressure by ~10mmHg within 5 to 10 minutes.[5,11] (Figure 4) These patients did not receive concurrent fluid therapy as no IV line could be placed. When fluid resuscitation therapy was given concurrently, systolic blood pressures rose even faster by nearly 20mmHg within 10 minutes. (Figure 5) The work of breathing associated with the ITD-7 was measured and it was not significantly greater than the amount of work needed to breathe naturally at rest.[4] Due to the relatively small increase in work needed to breathe through the ITD-7, it was generally well tolerated for at least 30 to 60 minutes.

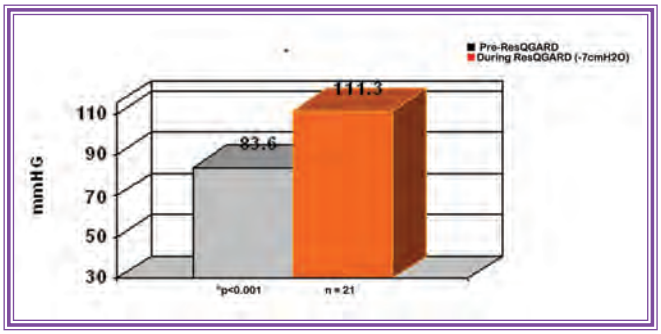

Figure 5: *IDT-7 (ResQGARD) increases systolic blood pressure in hypotensive patients treated by paramedics outside the hospital*

How to use it

The ITD-7 is simple to apply and can be used with either a mouth piece or a face mask as shown in Figure 1. When used with a facemask, it can be held in place by an optional head strap. After inserting the ITD-7 into the mouth or applying the facemask and ITD-7, instruct the hypotensive Soldier to breath in through the device as they normally would, at a rate of ~12 times/minute. The user will feel the slight resistance with each inspiration, which is helping to increase blood return to the heart and increase blood pressure. Oxygen can be applied at up to 6L/min to the small nipple attached to the ITD-7. The ITD-7 can be used on Soldiers getting other therapies. A resuscitator bag can be attached to the ITD-7 if needed to provide assisted ventilations. Remove the ITD-7 if it causes respiratory distress, or after the blood pressure has been restored. The device can be used for 30 to 60 minutes. Longer application can be performed as long as the Soldier does not complain of difficulty breathing.

When to use it

Indications

The ITD-7 should be used in spontaneously breathing symptomatic Soldiers who are hypotensive (systolic blood pressure <110mmHg), feel faint, or feel lightheaded. The ITD-7 can be used to treat multiple causes of low blood pressure as described in Table 1.

Table 1: Causes of Hypotension Treatable with the ITD-7

Blood loss
Heat stroke
Dehydration
Severe orthostatic hypotension
Other potentially reversible causes of low blood pressure and low blood flow – including early stages of sepsis

If there is ongoing uncontrolled bleeding, stop the bleeding before applying the device. The ITD-7 should not be used in Soldiers with an open chest wound or unconscious Soldiers unless they are intubated, still breathing, and hypotensive. The ITD-7 can be used when lying, sitting, standing, or walking. The ITD-7 may be particularly helpful in the setting of severe limb injuries after a tourniquet has been applied.

Table 2: Contraindications to ITD-7 Application

Uncontrolled bleeding
An open chest wound
Lack of spontaneous respiration
Agonal breathing at rates of < 8 breaths/min
Complaints of difficulty breathing
Congestive heart failure, when causing hypotension

Summary

The ITD-7 can be used to treat symptomatic hypotensive Soldiers who are breathing spontaneously. It is FDA-approved as a circulatory enhancer for the treatment of relative hypovolemia and hypotension suffered by people as a result of reduced central blood volume. It is lightweight, easy to use, durable, and well tolerated. It can be used to buy time by providing a critical bridge to more definitive repair of the primary injury.

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For correspondence contact:
Don Parsons, PA-C
Department of Combat Medic Training
Ft Sam Houston, TX 78234-6115
Phone: 210-221-5235
Email: Donald.Parsons@AMEDD.ARMY.MIL

Donald L. Parsons is a retired LTC who was a Special Forces medic back in the early 70s. He is currently a physician assistant and assigned as the Deputy Director of the Department of Combat Medic Training at Ft Sam Houston TX.

Dr. Vic Convertino is senior research physiologist at the U.S. Army Institute of Surgical Research at Ft Sam Houston, TX. He received Baccalaureate degrees in mathematics and physical education at the California State University at San Jose, a Masters degree in exercise science and a PhD degree in physiology at the University of California at Davis. His professional career has taken him to positions at NASA's Ames Research Center, the Stanford University School of Medicine, the University of Arizona, NASA's Kennedy Space Center, and the U.S. Air Force Research Laboratory before assuming his present position as manager for the Advanced Capabilities for Combat Medics Task Area in the Combat Casualty Care Research Program for the U.S. Army Medical Research and Materiel Command. Dr. Convertino has published over 200 peer-reviewed manuscripts, invited reviews, and chapters in the scientific literature with a focus on human physiological responses to stress conditions.

Ahamed Idris, Department of Emergency Medicine, University of Texas Southwestern, Dallas, TX

Stephen Smith, Department of Emergency Medicine, University of Minnesota, Minneapolis, MN

David Lindstrom, EMS Medical Director, Lucas County, OH

Brent A. Parquette, NREMT-P is a FF/Paramedic with the Toledo Fire and Rescue Department (19yrs) 1988-2007, Training and Quality Assurance Manager Lucas County EMS

Dr. Tom Aufderheide is a Professor of emergency medicine, Associate Chair of Research Affairs, and Director of the NIH-funded Resuscitation Research Center located in the Department of Emergency Medicine at the Medical College of Wisconsin. He is an internationally recognized researcher in the field of emergency medicine. The focus of Dr. Aufderheide's research has been improving hemodynamics in states of profound shock. He has served in many leadership roles with the National American Heart Association, to include chairing the Basic Life Support Subcommittee, being a member of ILCOR, founding member of the First Aid Task Force, and Basic Life Support Science Editor. Dr. Aufderheide is currently the principal investigator of a number of NIH-funded clinical trials examining promising interventions in cardiac arrest and acute neurological emergencies.